

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC, and
LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 23-377-JLH

ANDA CASE

UNREDACTED PUBLIC VERSION

JOINT [PROPOSED] FINAL PRETRIAL ORDER
WITH EXHIBITS (1-16)

Pursuant to Federal Rule of Civil Procedure 16, this matter comes before the Court at a final pretrial conference to be held on Tuesday, February 25, 2025. The parties are Plaintiffs Ingenus Pharmaceuticals, LLC (“Plaintiff” or “Ingenus”, and Leiutis Pharmaceuticals LLP (“Leiutis”) (together, “Plaintiffs”) and Defendant Accord Healthcare, Inc. (“Defendant” or “Accord”). Pursuant to D. Del. LR 16.3, Plaintiffs and Defendant (“the Parties”) hereby submit for the Court’s approval this proposed Final Pretrial Order governing the bench trial of the above-captioned matter, which is scheduled to begin on March 24, 2025.

This Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

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I. NATURE OF THE ACTION [D. DEL. LR 16.3(C)(1)]

1. This is an action alleging patent infringement arising under the patent laws of the United States, Title 35, United States Code based on Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA").

2. Plaintiff is the holder of New Drug Application (NDA) No. 212501, which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide solution for intravenous use ("NDA Product"). The active ingredient in Plaintiffs' Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under New Drug Application No. N212501.

3. The '952 Patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021.

4. Leiutis and Ingenus were originally co-owners and assignees of the '952 Patent. By assignment in June, 2024, Ingenus is now the exclusive owner of the '952 Patent.

5. Pursuant to 21 U.S.C. § 355(b)(1), the '952 Patent was submitted to FDA with NDA No. 212501 and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

6. Plaintiffs are currently asserting Claims 1-4 of the '952 Patent ("the Asserted Claims").

7. By letter dated February 20, 2023 (the "Notice Letter"), Defendant informed Plaintiffs that it had submitted ANDA No. 218250 ("Accord's ANDA") to the FDA under Section

505(j)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2), seeking approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiffs’ NDA Product prior to the expiration of the ’952 Patent.

8. Accord’s ANDA included a Paragraph IV certification alleging, *inter alia*, that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products that are the subject of Accord’s ANDA.

9. On April 3, 2023, Plaintiffs commenced this action, case number 23-377-JLH (the “Action”) against Defendant within forty-five (45) days after receiving the Notice Letter by filing a Complaint. Plaintiffs asserted that Defendant was infringing under 35 U.S.C. § 271(e)(2)(A) by its submission of ANDA No. 218250 prior to the expiration of patents-in-suit. (D.I. 1) Plaintiffs also asserted that if Accord’s ANDA were to be approved, then Defendant’s manufacture, use, sale and/or offer to sell in the United States, and/or importation into the United States, of the Accord ANDA Product would infringe the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c). (*Id.*)

10. On June 20, 2023, Defendant files its Answer and Counterclaims denying infringement and alleging counterclaims of noninfringement and patent invalidity with respect to the patents-in-suit. (D.I. 11)

11. On July 7, 2023, Plaintiffs filed their Answer to Defendant’s Counterclaims (D.I. 16)

12. The 30 month stay expires August 20, 2025.

II. JURISDICTION [D. DEL. LR 16.3(C)(2)]

13. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271. The subject matter jurisdiction of the Court in this matter is not disputed for purposes of this Action only. Defendant also does not contest personal

jurisdiction or venue for the purposes of this Action only.

III. UNCONTESTED FACTS [D. DEL. LR 16.3(C)(3)]

14. A statement of uncontested facts is attached as **Exhibit 1**. These facts are not disputed or have been agreed to or stipulated to by the Parties. These facts require no proof at trial and upon entry of this Pretrial Order, become part of the evidentiary record in this case.

IV. CONTESTED FACTS [D. DEL. LR 16.3(C)(4)]

15. Plaintiffs' statement of issues of fact to be litigated, with a brief statement of what Plaintiffs intend to prove, is attached as **Exhibit 2**.

16. Defendant's statement of issues of fact to be litigated, with a brief statement of what Defendant intends to prove, is attached as **Exhibit 3**.

V. STATEMENT OF ISSUES OF LAW [D. DEL. LR 16.3(C)(5)]

17. Plaintiffs' statement of issues of law to be litigated is attached hereto as **Exhibit 4**.

18. Defendant's statement of issues of law to be litigated is attached hereto as **Exhibit 5**.

VI. LIST OF PREMARKED EXHIBITS [D. DEL. LR 16.3(C)(6)]

A. Trial Exhibits

19. The list of exhibits, subject to continued meeting and conferring in advance of and during trial, that Plaintiffs and Defendant may ultimately offer jointly, is attached hereto as **Exhibit 6**. These exhibits are identified by the prefix JTX.

20. The list of exhibits that Plaintiffs may offer, including Defendant's objections thereto, is attached hereto as **Exhibit 7**. These exhibits are identified by the prefix PTX.

21. The list of exhibits that Defendant may offer, including Plaintiffs' objections thereto, is attached hereto as **Exhibit 8**. These exhibits are identified by the prefix DTX.

22. The parties shall provide the Court with electronic copies of exhibits described in **Exhibits 6–8** (either by USB drive or via email to JLH_civil@ded.uscourts.gov) on Friday, March 21, 2025.

23. The Pretrial Order contains the maximum universe of exhibits to be used by any party for direct, cross (other than solely for impeachment), and re-direct examinations as well as all objections to the admission of such exhibits. Exhibits not listed will not be admitted unless good cause is shown.

24. Each party reserves the right to offer exhibits set forth on the other party's exhibit list, even if not set forth on its own exhibit list. All objections to such exhibits are preserved, regardless of whether such exhibits also appear on the other party's exhibit list. Any trial exhibit, once admitted, may be used equally by either party subject to any limitations as to its admission into evidence.

25. The parties reserve their rights to raise all objections to exhibits as set forth on the trial exhibit lists. The listing of a trial exhibit does not constitute an admission as to the admissibility of the trial exhibit (i.e., a waiver of any applicable objection). Each party reserves the right to object to the relevance or admissibility of any evidence offered by the other party (or jointly), at the time such evidence is offered, in view of the specific context in which such evidence is offered, or for any other reason as set forth in the Federal Rules of Evidence or other applicable principles of law.

26. The parties agree that if any party removes or otherwise withdraws an exhibit from its trial exhibit list, the other party may amend its trial exhibit list to include that same exhibit. The parties also agree that the amending party may make objections to such added trial exhibit, other than an objection based on untimely listing.

27. The parties agree that any description of a document on a trial exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.

28. The schedule of exchange of exhibits is discussed below.

29. Other than trial exhibits jointly designated by the parties in **Exhibit 6** and any supplements thereto, or as otherwise agreed by the parties, no exhibit shall be admitted unless offered into evidence through a witness, subject to the Court's ruling on any objections as to admissibility and the witness's ability to testify concerning said exhibit. At some point before the completion of the party's case-in-chief, any party that has used an exhibit with a witness and wishes for that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number. Failure to raise an objection to an exhibit at trial shall be considered a waiver of said evidentiary objection.

30. The parties agree that exhibits used for impeachment purposes may be admitted into evidence whether or not they are included in the exhibit lists. The parties reserve the right to object on evidentiary or discovery grounds to any such exhibit if used at trial.

31. Exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided they are referenced by a witness through live testimony or by deposition designation. Each party agrees that complete legible copies of documents may be offered and received into evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or if in the circumstances it would be unfair to admit the copy in lieu of the original. Complete legible copies of United States and foreign patents and/or applications, and the contents of associated file histories, may be offered and received into evidence in lieu of certified copies thereof, subject to

all other objections which might be made to the admissibility of certified copies.

B. Demonstrative Exhibits

32. Exhibits that the parties intend to use at trial solely for demonstrative purposes (i.e., those created for purposes of trial, as distinguished from physical exhibits that exist independent of trial in this Action that a party may wish to use at trial) without admitting into evidence (“demonstrative exhibits”) do not need to be described on their respective lists of trial exhibits.

33. Each demonstrative exhibit shall clearly indicate on the face of the demonstrative exhibit, if practicable, all information sources (including, if available, trial exhibit numbers) that form the basis for the demonstrative exhibit. If not practicable to indicate the sources on the face of the demonstrative exhibit itself, an identification of the sources shall accompany the demonstrative exhibit.

34. Plaintiffs’ demonstrative exhibits will be identified with unique PDX numbers. Defendant’s demonstrative exhibits will be identified with unique DDX numbers.

35. Demonstrative exhibits, while not substantive evidence, shall be submitted to the Court at the end of trial and included in the record for appeal.

36. Each party shall serve on opposing counsel by electronic mail (for files having a size of less than 10 MB) and/or by online file transfer (for files having a size of 10 MB or greater) full color copies (or videos, for the case of animations) of any demonstrative exhibits that each party intends to use at trial during opening statements or during direct examination of a witness according to the schedule below. For irregularly sized physical demonstrative exhibits, the party seeking to use the demonstrative exhibit will provide a color representation as a PDF of 8.5 x 11 inch copies of the demonstrative exhibit and make the original available for inspection by the opposing party.

37. For demonstrative exhibits to be used in connection with opening statements, each

party shall exchange such demonstrative exhibits by 12:00pm ET the day before opening statements. The party receiving identification of demonstrative exhibits for opening statements will inform the party identifying the demonstrative exhibits of any objections by 4:00 pm ET on the day before opening statements, and the parties will meet and confer as soon as possible thereafter to resolve such objections, but in any event by 5:00 pm ET that same day.

38. For demonstrative exhibits to be used in connection with direct examination of a witness, each party shall exchange such demonstrative exhibits by 7:00 pm ET on the calendar day before such direct examination is expected to take place. The party receiving identification of demonstrative exhibits for direct examination will inform the party identifying the demonstrative exhibits of any objections by 9:00 pm ET on the day of receipt, and the parties will meet and confer as soon as possible thereafter to resolve such objections, but in any event by 10:00 pm ET that evening. If good faith efforts to resolve the objections fail, the party objecting to the demonstrative exhibits shall bring its objections to the Court's attention at the beginning of the next trial day.

39. The parties agree that notice of a party's intended use of blow-ups (enlargements) of a single trial exhibit and of ballooning, excerption, highlighting, etc. of such an exhibit need not be given and need not be exchanged as demonstratives, as long as the party has identified its intent to use the trial exhibits and/or deposition testimony according to the provisions of this Order.

40. For the avoidance of doubt, the notification provisions for demonstrative exhibits do not apply to demonstrative exhibits created in the courtroom during testimony, or to demonstratives used for cross-examination or impeachment purposes, which do not need to be provided to the other side in advance of their use. A party shall not be precluded from using such demonstrative exhibits if used for cross-examination or impeachment purposes for the sole reason that it was not provided before cross-examination of a witness. The advance notification

provisions for demonstrative exhibits also do not apply to demonstrative exhibits used in closing arguments (to the extent closing arguments are requested by the Court), which do not need to be provided to the other side in advance of their use.

VII. WITNESSES [D. DEL. LR 16.3(C)(7)]

41. Plaintiffs' list of fact and expert witnesses it may call at trial, either live or by deposition, and Defendant's objections to Plaintiffs' witnesses, are attached hereto as **Exhibit 9**. The *curricula vitae* of Plaintiffs' expert witnesses are attached hereto as **Exhibit 10**.

42. Defendant's list of fact and expert witnesses it may call at trial, either live or by deposition, and Plaintiffs' objections to Defendant's witnesses, are attached hereto as **Exhibit 11**. The *curricula vitae* of Defendant's expert witnesses are attached hereto as **Exhibit 12**.

43. Any witness not listed as described in **Exhibits 9 or 11** will be precluded from trial.

44. The *curricula vitae* of live witnesses a party intends to call at trial may be submitted at the time of the pretrial conference.

45. The listing of a witness on a party's witness list does not require that party to call that witness to testify, either in person or by deposition, nor shall it constitute an admission as to the availability or unavailability of that witness to appear live at trial.

46. Each party shall identify by electronic mail a good faith order of all of its live trial witnesses by 7:00 pm ET three (3) weeks ahead of the start of trial. Additionally, the parties agree they will timely notify the other party if there are any anticipated changes to the order of live trial witnesses after the disclosures described in this paragraph and before the start of trial.

47. The identification of witnesses is discussed below. Except as permitted under D. Del. LR 43.1 or by express permission of the Court, once tendered for cross examination, no witness shall communicate with anyone else regarding the substance of the witness's testimony until such time as cross examination is concluded. If the witness will be called to the stand to

testify at a later time during the trial, once the witness has completed his or her cross examination, that witness can speak with counsel before taking the stand to testify at a later time during the trial.

A. Deposition Designations

48. Deposition testimony that Plaintiffs may offer into evidence, together with Defendant's counter-designations and the parties' respective objections, is identified in **Exhibit 13** hereto. Deposition testimony that Defendant may offer into evidence, together with Plaintiffs' counter-designations and the parties' respective objections, is identified in **Exhibit 14** hereto. Deposition testimony to be used solely for impeachment but not admitted into evidence need not be identified to the other side in advance of its use.

49. The exchange of deposition designations is discussed below. If deposition testimony is to be presented by video, then the party playing the designated testimony shall also serve the other party with actual video clips of all testimony to be played by 7:00 p.m. ET the calendar day before the witness is to be called at trial.

50. If there are objections that remain to be resolved after the parties meet and confer, the party calling the witness by deposition shall, no later than 6:00pm one (1) calendar day before the witness is to be called at trial, submit on behalf of all parties: (i) a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter-designations, and pending objections; and (ii) a cover letter clearly identifying the pending objections as well as a brief indication (i.e., no more than one sentence per objection) of the basis for the objection and the offering party's response to it. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.

51. To the extent that deposition designations or counter-designations are admitted into evidence, they must either be played by video or read in open court, unless the Court prefers to

accept and take any such submissions under advisement (with each party being charged for the playing time of their respective portions of the video designations). If a party opts to introduce deposition testimony, any counter-designation of that same witnesses' testimony must be submitted in the same medium, and the testimony designated by both parties will be played or read consecutively in the sequence in which the testimony was originally given at deposition. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with three (3) complete copies of the transcript of the designations and counter-designations that will be read or played, with the specific designations highlighted. To the extent deposition designations are read or played in open court, each party will be charged the time taken to read or play its designations. Prior to the introduction of deposition designations or counter-designations, counsel for the introducing party may provide a short introduction to the Court about the identity of the witness and subject matter of deposition testimony, which introduction the parties agree is not evidence and the time for which will be charged against that party.

52. All irrelevant and redundant colloquy between counsel and objections will be eliminated when the deposition transcript is presented at trial. However, any objections that a party intends to seek a ruling on from the Court will be made at trial.

53. Each party may move an exhibit into evidence at the end of a witness's testimony or at another reasonable time.

54. The listing of a deposition designation does not constitute an admission as to the admissibility of the testimony nor is it a waiver of any applicable objection.

B. Objections to Expert Testimony

55. The parties request that the Court rule at trial on objections to expert testimony as outside the scope of prior expert disclosures, taking time from the losing parties' trial presentation to argue and decide such objections.

VIII. EXCHANGES

56. For their infringement case, Plaintiffs will identify (1) the witnesses they intend to call live; (2) the deposition designations they intend to use; and (3) the exhibits they intend to use with each witness or deposition transcript by 12:00 Eastern on Saturday, March 22.

57. For their case, Defendants will identify (1) the witnesses they intend to call live; (2) the deposition designations they intend to use; and (3) the exhibits they intend to use with each witness or deposition transcript; as well as (4) objections and counter-designations to Plaintiffs' materials by 5:00 Eastern on Saturday, March 22.

58. For their rebuttal case on validity, Plaintiffs will identify (1) the witnesses they intend to call live; (2) the deposition designations they intend to use; and (3) the exhibits they intend to use with each witness or deposition transcript; and (4) objections and counter-designations to Defendants' materials by 12:00 Eastern on Sunday, March 23.

59. The parties will identify all remaining objections and counter-designations by 3 PM on Sunday, March 23.

60. The parties will meet and confer to discuss all remaining issues by 4 PM on Sunday, March 23.

IX. BRIEF STATEMENT OF INTENDED PROOFS [D. DEL. LR 16.3(C)(8)-(10)]

61. In support of their claims and in addition to the facts not in dispute, Plaintiffs expect to offer the proofs set forth in **Exhibit 15**.

62. In support of its claims and in addition to the facts not in dispute, Defendant expects to offer the proofs set forth in **Exhibit 16**.

X. PROPOSED AMENDMENTS TO THE PLEADINGS [D. DEL. LR 16.3(C)(11)]

63. No parties seek to amend the pleadings at this time.

XI. CERTIFICATION OF SETTLEMENT DISCUSSIONS [D. DEL. LR 16.3(C)(12)]

64. The parties certify that they have engaged in a good faith effort to explore the resolution of the controversy by settlement. A settlement has not yet been reached.

XII. MISCELLANEOUS ISSUES

A. Motions in Limine and *Daubert* Motions and Experts

65. There are no motions *in limine* and no *Daubert* motions in this Action.

66. The parties stipulate that the opposing experts are qualified and accepted as experts without objection.

B. Damages and Other Remedies

67. The parties do not intend to seek damages at this time, except all parties reserve the right to seek attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 285. Plaintiffs also reserve the right to seek damages if Defendant manufactures, uses, sells and/or offers to sell in the United States, and/or imports into the United States, any of the Accord ANDA Product prior to the expiration date of any of the patents-in-suit. Defendant reserves the right to object to any relief sought by Plaintiffs.

68. Plaintiffs request the following relief from the Court:

- An order that each of the asserted claims of the patents-in-suit is infringed (directly and/or indirectly) and not invalid;
- An order that the effective date of any approval of Accord's ANDA No. 218250 be not earlier than the expiration of the patent-in-suit or any later expiration of any patent term extension or exclusivity for those patents to which Plaintiffs are or become entitled;
- Injunctive relief, as appropriate, against any infringement of the patents-in-suit by Defendant, their officers, agents, attorneys, and employees, and those acting

in privity or contract with them, precluding them from manufacturing, using, selling and/or offering to sell in the United States, and/or importing into the United States the Accord ANDA Product;

- A grant of such other and further relief as this Court may deem just and proper.

69. Defendant requests the following relief from the Court:

- An order that each of the asserted claims of the patents-in-suit is not infringed (directly and/or indirectly) and/or is invalid;
- An order denying any injunctive relief requested by Plaintiffs;
- Any other and further relief as the Court may deem just and proper.

C. Expected Duration and Scope of Trial

70. Trial is scheduled to begin on March 24, 2025 and to last three (3) days. The parties propose that the time that a party is presenting opening statements (to the extent opening statements are made orally), or examining or cross-examining witnesses (whether live or by deposition), will be counted as the time of that party. Time spent arguing objections in open Court will be assessed against the party that receives an adverse ruling concerning the objection.

D. Setup of Electronic and Computer Devices

71. The parties request that the Court grant access to the Courtroom on the business day before trial begins, i.e., Friday, March 21, 2025 (or whatever date is convenient to the Court), for the purposes of setting up electronic and computer devices. To the extent both parties are using common equipment in the Courtroom, the parties will share the cost of that equipment.

E. Type of Trial

72. This is a bench trial.

F. Order of Proof

73. This proposed order of proof assumes that at least some infringement issues remain

unresolved by the time of trial, whether by stipulation or otherwise.

74. Opening statements will be delivered in the following order: Plaintiffs then Defendant.

75. Plaintiffs will present their entire case in chief on issues of infringement, including asserted patents-in-suit and technology background. Defendant then will present its rebuttal to Plaintiffs' case in chief on issues of infringement, any additional technology background, and issues of patent invalidity. This includes presenting evidence on objective indicia of nonobviousness so long as Plaintiffs commit to identifying the objective indicia of nonobviousness they will be presenting and the witnesses who will be presenting it, by no later than Sunday March 22 at 12:00 Eastern with their invalidity materials.

76. Plaintiffs then will present their rebuttal to Defendant's case in chief on issues of patent invalidity, including presenting evidence on objective indicia of nonobviousness.

G. Daily List of Admitted Exhibits

77. The parties will confer each day to discuss the list of admitted exhibits used during the trial day. The parties will jointly coordinate with Court staff to ensure the Court and all parties have an accurate list of admitted exhibits, and in the event of a dispute, timely raise any issues in the morning.

H. Trial Transcript Errata

78. The parties will meet and confer regarding an appropriate schedule for submission of corrections to the trial transcript.

I. Post-Trial Briefing

79. The parties propose the following post-trial briefing schedule:

Brief	Pages	Due Date
Opening (on issues for which party bears burden of proof)	50	April 25
Responsive	50	May 16
Reply	25	May 28

80. Only admitted trial exhibits and demonstratives actually used in Court may be relied upon in post-trial briefing.

81. No appendices shall be submitted with any post-trial briefs.

82. Trial exhibits shall be referred to by exhibit number (PTX-, DTX-, or JTX-).

J. Submission of Exhibits After Trial

83. The parties shall submit electronic copies of admitted exhibits to the Court within seven (7) days of the filing of the last post-trial brief and any other submissions that the Court requires.

IT IS SO ORDERED this ____ day of _____, 2025.

The Honorable Jennifer L. Hall
United States District Judge

Dated: February 19, 2025

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Daniel A. Taylor

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